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	APPLICATION NO.	FILING DATE	FIRST NAMED INV	ENTOR	AT	TORNEY DOCKET NO.
	09/627,75	3 107/28/	00 LIVAK .		, K	426405
Γ	022896	00000			EXAMINER	
		AN, PATENT	HM12/0622 ADMINISTRATOR	•	RILEY, J	
	APPLIED BIOSYSTEMS 850 LINCOLN CENTRE DRIVE			. [	ART UNIT	PAPER NUMBER
	FOSTER CITY CA 94404				1656	Oj
					DATE MAILED:	06/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

		Application No.	Applicant(s)					
	Office Action Summary	09/627,753	LIVAK ET AL.					
	Office Action Summary	Examiner	Art Unit					
		Jezia Riley	1656					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
THE - Exte after - If the - If NC - Failt - Any	ORTENED STATUTORY PERIOD FOR F MAILING DATE OF THIS COMMUNICAT nsions of time may be available under the provisions of 37 ( SIX (6) MONTHS from the mailing date of this communicat period for reply specified above is less than thirty (30) days period for reply is specified above, the maximum statutory tre to reply within the set or extended period for reply will, by reply received by the Office later than three months after the ad patent term adjustment. See 37 CFR 1.704(b).	ION.  CFR 1.136 (a). In no event, however, mion.  s, a reply within the statutory minimum operiod will apply and will expire SIX (6) y statute, cause the application to become	ay a reply be timely filed  f thirty (30) days will be considered timely.  MONTHS from the mailing date of this communication.  te ABANDONED (35 U.S.C. § 133).					
1)⊠	Responsive to communication(s) filed o	n <u>17 May 2001</u> .						
2a) <u></u> □	This action is <b>FINAL</b> . 2b)	This action is non-final.						
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims								
<b>4</b> )⊠	4)⊠ Claim(s) <u>39 and 40</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)	Claim(s) is/are allowed.							
6)⊠	Claim(s) <u>39 and 40</u> is/are rejected.							
7)	Claim(s) is/are objected to.							
8)	Claims are subject to restriction	and/or election requirement						
Application Papers								
9)[	☐ The specification is objected to by the Examiner.							
10)	☐ The drawing(s) filed on is/are objected to by the Examiner.							
11)	☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved.							
12)	2) The oath or declaration is objected to by the Examiner.							
Priority (	under 35 U.S.C. § 119		•					
13)	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)	a) ☐ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority docu	ıments have been received.						
	2. Certified copies of the priority documents have been received in Application No							
* 9	<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
	14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).							
٠./١		· ·						
Attachmen	• ,	_						
16) 🔲 Not	ice of References Cited (PTO-892) ice of Draftsperson's Patent Drawing Review (PTO- ormation Disclosure Statement(s) (PTO-1449) Paper	948) 19) 🔲 Not	rview Summary (PTO-413) Paper No(s) ce of Informal Patent Application (PTO-152) er:					

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#### **DETAILED ACTION**

# Response to Remarks

1. Applicants' arguments and amendments, filed on 5/17/01, have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (EPO 0 229 943, 1987) in view of Urdea et al. (4,775,619).

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Heller et al. discloses fluorescent probes, for polynucleotide hybridization assays, comprising donor and acceptor fluorophores. Maximum observed acceptor fluorophore emission was also found to be dependent upon hybridization of the probe to its complementary target sequence (page 6, lines 29-31). With proper spacing (between the fluorophores) an exceptionally high value for fluorescent emission by the acceptor fluorophore can be obtained (page 6-7, bridging paragraph and page 7-8, bridging paragraph). Fluorescein is a particularly desirable donor moiety. A list of other fluorophores is given on page 10 paragraph 2. Page 14 describes the assay procedure where it is stated that to obtain the maximum benefit of the invention, it is preferred to employ the probes in conjunction with heterogeneous assays in which the target DNA or RNA is hybridized to a support.

Urdea et al. discloses methods for diagnosis employing polynucleotides having oligonucleotide sequences substantially homologous to a sequence of interest. Methods are provided for the detection of specific nucleotide sequences employing a solid support (col. 2-9).

Therefore it would have been obvious at the time the invention was made to provide a labeled probe attached to a solid support as disclosed by Urdea for the methods of Heller. The motivation is that hybridization assay can be carried out by attaching probes to a surface. Detection of sequences has involved various hybridization techniques requiring the binding of a polynucleotide sequence to a support and employing labeled probe (Urdea et al. col. 1 and 17).

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## **Double Patenting**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 5. Claims 39 and 40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 5,876,930 and claims 1-12 of U.S. Patent No. 6,030,787. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are claiming the same method but not of the same scope.
- 6. No claim is allowed.
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is (703) 305-6855. The Examiner may normally be reached Monday through Friday, 0900 1700 EST. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Gary Jones, may be reached at (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix Receptionist whose telephone number is (703) 308-0196.

Any necessary fax can be sent to (703) 308-4242.

JEZIA RILEY
PRIMARY EXAMINER